510(k) Summary

OCT 9 2012

Device Trade Name: Cross-Over Acetabular Shell and Liner

Manufacturer:
StelKast, Inc.
200 Hidden Valley Road
McMurray, PA 15317

Contact:
Mr. David Stumpo
Vice President of Product Development
Phone: 724.731.2208
Fax: 724.941.5987
dstumpo@stelkast.com

Prepared by:
Musculoskeletal Clinical Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
Fax: (202) 552-5798

Date Prepared: September 7, 2012

Classification: 21 CFR 888.3358, Hip joint metal/polymer/metal semiconstrained porous-coated uncemented prosthesis

Class: II

Product Codes: OQG, OQH, OQI, LPH, LWJ, JDI, MAY, LZO

Indications For Use:
The Cross-Over Acetabular Shell and Liner are intended for use in reconstruction of the articulating surface of the acetabular portion of the hip that is severely disabled and/or very painful resulting from:

1. Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip Arthroplasty.

The Cross-Over Acetabular Shell and Liner are used as part of the Provident Hip Systems. The components of this hip system are intended for cementless fixation.

Device Description:
The Cross-Over Acetabular Shell and Liner will be used as part of a complete total hip system in conjunction with a femoral head and femoral stem in total hip arthroplasty.

The Cross-Over Acetabular Shell is made of titanium alloy with a commercially pure titanium plasma spray coating. The Cross-Over Liner is made of polyethylene blended with Vitamin E. The liner is available in both non-hooded and hooded options.

Predicate Devices:
Comparative information presented in the 510(k) supports the substantial equivalence of the Cross-Over Acetabular Shell and Liner with respect to their indications for use, design, materials, and performance.

This 510(k) demonstrates the substantial equivalence of the Cross-Over Acetabular Shell and Liner to the following predicate devices:

- Acetabular Shells in the Stelkast Provident Hip System (K001745), and
- EXp Acetabular Liner (K094035)

These acetabular shells and liners have the same intended use and general design, are available in a similar size range, and are made of the same materials.

Preclinical Testing:
Non-clinical testing was performed on the Cross-Over Acetabular Shell and Liner to assess the interconnection mechanism between the shell and liner (i.e., disassembly force, lever-out torque, and rotational failure torque). The results of the performed tests demonstrate that the Cross-Over Acetabular Shell and Liner are substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 9 2012

StelKast Company
% Mr. David Stumpo
Vice President of Product Development
200 Hidden Valley Road
McMurray, Pennsylvania 15317

Re: K122773
Trade/Device Name: Cross-Over Acetabular Shell and Liner
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip Joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: OQG, OQH, OQI, LPH, LWJ, JDI, MAY, LZO
Dated: September 7, 2012
Received: September 13, 2012

Dear Mr. Stumpo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122773

Device Name: Cross-Over Acetabular Shell and Liner

The Cross-Over Acetabular Shell and Liner are intended for use in reconstruction of the articulating surface of the acetabular portion of the hip that is severely disabled and/or very painful resulting from:

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Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122773